

REMARKS

Claim Rejections - 35 U.S.C. § 112

The Examiner has rejected claims 1, 3-4, 12-16, 22 and 24-25 pursuant to 35 U.S.C. § 112 ¶¶ 1-2 because the Examiner argues that the specification and claims are not clear whether the transition radii and balloon diameters refer to deflated or inflated states. In response to the Examiner's comments, Applicants hereby submit a second declaration by David G. Burton.

As explained by Mr. Burton, paragraph [0036] of the application explains that the enlarged radii described in the specification and claimed in the claims may be measured when the medical balloon is unfolded. (Burton Second Decl. ¶ 3). One of ordinary skill in the art understands that in order to thread a medical balloon through an artery, it must be deflated and then wrapped around itself to form a small diameter profile. (Burton Second Decl. ¶ 3). A description of this is provided in the background section in paragraph [0008]. (Burton Second Decl. ¶ 3). Thus, the reference to measuring the radii in the unfolded state clearly refers to the deflated state before the balloon has been folded for insertion through an artery. (Burton Second Decl. ¶ 3). This is also described in paragraph [0047] where a conventional balloon 1300 is compared before inflation (Figure 13A) and after inflation (Figure 13B) to an enlarged radii balloon 1350 before inflation (Figure 13C) and after inflation (Figure 13D). (Burton Second Decl. ¶ 3). Thus, one of ordinary skill in the art would understand the references in the specification and the claims to transition radii to refer to radii before the balloon is inflated. (Burton Second Decl. ¶ 3).

Mr. Burton also explains that the specification describes in paragraphs [0002]-[0005], and it is recited in the claims, that the inventions of the application relate to a dilation catheter. (Burton Second Decl. ¶ 4). As described in the background section of the specification, dilation catheters are used to apply pressure against the interior of a biological conduit. (Burton Second Decl. ¶ 4). One of ordinary skill in the art understands that these types of catheters use an inelastic balloon in order to withstand very high pressures without uncontrollably expanding to an unpredictable

diameter. (Burton Second Decl. ¶ 4). As a result, the diameter of a medical balloon on a dilation catheter is substantially the same both in the deflated state and the inflated state. (Burton Second Decl. ¶ 4). This is illustrated graphically in Figures 13A-D, where Figures 13A and 13C are shown before inflation and Figures 13B and 13D are shown after inflation. (Burton Second Decl. ¶ 4). As shown, the diameter of the balloons does not change significantly from the deflated state to the inflated state. (Burton Second Decl. ¶ 4). As explained, this is important so that the physician using the dilation catheter will know beforehand what diameter the balloon will expand to regardless of the pressure applied to the balloon. (Burton Second Decl. ¶ 4). Thus, one of ordinary skill in the art would understand the references in the specification and the claims to balloon diameters to refer to a balloon having the specified diameter both in the deflated and inflated states. (Burton Second Decl. ¶ 4).

Accordingly, because one of ordinary skill in the art would understand the scope of the claims from the description provided in the specification, the Examiner may withdraw the § 112 rejections.

Claim Rejections - 35 U.S.C. § 103

The Examiner has rejected claims 1, 3-4, 12-16, 22 and 24-25 as being unpatentable pursuant to 35 U.S.C. § 103(a) over U.S. Patent No. 2003/0139762 (“Lee”) in view of U.S. Patent No. 5,797,878 (“Bleam”).

The Examiner’s comments in the response to arguments seems to reflect a misunderstanding of the transition that Applicants have claimed. The Examiner appears to argue that Applicants have presented a mere argument of semantics. (“Bleam simply uses different language to describe the process of smoothing the transition between the working length and tapers.” “Applicant’s arguments fail to specifically point out structural differences between the claimed invention and cited art.”). However, Applicants respectfully submit that clear structural differences have been identified by Applicants that are not disclosed by either Lee or Bleam. As described in paragraph [0036] and shown in Figure 2, the claimed transition is a radius 254 which may be represented by a scribed circle 255 at the working length-

to-taper transition and/or the taper-to-neck transition. This is unrelated to the angle of the taper. Indeed, two different tapers defined by different angles could have the same radii at the transitions, and two different tapers defined by the same angle could have different radii at the transitions. Thus, the radii at the transitions and the angle of the taper are two structurally different things. In fact, as previously argued, neither Lee nor Bleam even refer specifically to the transition radii that Applicants have claimed, and neither reference discloses the specific numerical values that Applicants have claimed for these transition radii. Because Applicants' previous remarks remain responsive to the Examiner's rejection, Applicants repeat the prior arguments below.

In response to the Examiner's rejection, Applicants previously submit the declaration of David G. Burton dated June 7, 2010 as evidence of non-obviousness. In light of Mr. Burton's declaration, Applicants respectfully submit that the prior art of record does not disclose all of the limitations of Applicants' claims and Applicants' claims would not be readily apparent from the prior art. Therefore, Applicants respectfully submit that the claims in condition for allowance.

As explained by Mr. Burton, Lee relates to a method of making an angioplasty balloon. (Burton 6/7/2010 Decl. ¶ 3). Lee claims that an advantage of the manufacturing method is that low profile and flexibility are achieved. (¶ [0027], line 9; Burton 6/7/2010 Decl. ¶ 3). Specifically, Lee's manufacturing method involves inserting an inner tube 106 through a shortened outer tube 102 to form a slug 100, as shown in Figure 2. (¶ [0025]; Burton 6/7/2010 Decl. ¶ 3). The slug 100 is then placed in a mold and heated and pressurized to form a balloon. (¶ [0025]; Burton 6/7/2010 Decl. ¶ 3). In the finished balloon, the shortened outer tube 102 forms the working length 44, and the inner tube 106 forms the proximal and distal tapers 48, 50. (¶ [0025], lines 13-17; Burton 6/7/2010 Decl. ¶ 3). As a result, less tube material is provided to the tapers 48, 50 than to the working length 44. (¶ [0027], lines 1-3; Burton 6/7/2010 Decl. ¶ 3).

By contrast, the claimed inventions relate to a medical balloon with enlarged radii at the working length-to-taper transition and the taper-to-neck transition. (Burton 6/7/2010 Decl. ¶ 4). The enlarged radii provide smooth transitions from the working length to the taper and from the taper to the neck. (Burton 6/7/2010 Decl. ¶ 4). As a

result of the smooth transitions, lower forces are required to withdraw the balloon catheter through a delivery sheath or other conduit. (¶ [0044]; Burton 6/7/2010 Decl. ¶ 4). This advantage solves a number of potential problems. (Burton 6/7/2010 Decl. ¶ 4). Because medical balloons typically do not collapse easily after being inflated and deflated, conventional balloons can be difficult to pull back through a conduit after use. (Burton 6/7/2010 Decl. ¶ 4). This can make it more difficult for the physician to perceive problems; can result in more trauma to the patient; and can result in the catheter being damaged. (¶¶ [0011], [0044], [0045]; Burton 6/7/2010 Decl. ¶ 4). The claimed balloon catheter may overcome these problems because the enlarged radii reduce the force required to withdraw the balloon. (¶ [0044]; Burton 6/7/2010 Decl. ¶ 4).

As Mr. Burton explains, Lee does not relate to the balloon profile that the Applicants developed. (Burton 6/7/2010 Decl. ¶ 5). As explained above, Lee's balloon has tapers with a thinner wall thickness than the working length. (Burton 6/7/2010 Decl. ¶ 5). By contrast, the claimed inventions relate to enlarged radii at the transitions between the working length and the tapers, and the transitions between the tapers and the necks. (Burton 6/7/2010 Decl. ¶ 5). Not only is Lee related to an entirely different geometry than claimed inventions, but Lee does not even mention the transitions between the tapers and the working length and the necks. (Burton 6/7/2010 Decl. ¶ 5). Since Lee does not even refer to the relevant transitions, Lee also fails to specify any of the specific radii that Applicants discovered for the transitions. (Burton 6/7/2010 Decl. ¶ 5).

While Bleam generally recognizes the desirability of minimizing cross and recross forces (col. 2:31-34), Bleam solves this problem in a different way than the claimed inventions do. (Burton 6/7/2010 Decl. ¶ 6). The solution offered by Bleam is to change the angle α of the taper to make the tapered portions of the balloon more tapered. (Col. 5:53-55; 5:62-6:6; Burton 6/7/2010 Decl. ¶ 6). Bleam's preferred taper angle α is between 7° and 20°, 9° and 12°, or 10° and 11°. (Col. 6:52-56; Burton 6/7/2010 Decl. ¶ 6). However, this is not the solution that Applicants developed. (Burton 6/7/2010 Decl. ¶ 6). Instead, as noted above, the claimed inventions relate to a balloon where the radii at the transitions between the working length and the taper and between the taper and the neck region are enlarged—irrespective of the angle of the

taper. (Burton 6/7/2010 Decl. ¶ 6). Like Lee, Bleam does not even mention the transitions that the claimed inventions relate to. (Burton 6/7/2010 Decl. ¶ 6). Because Bleam doesn't mention the relevant transitions, Bleam also does not specify any dimensions for the transitions, much less the specific radii that Applicants discovered. (Burton 6/7/2010 Decl. ¶ 6).

In addition to the fact that the written descriptions of Lee and Bleam do not disclose anything about the transitions between the tapers and the working length and the necks, the figures of Lee and Bleam do not provide a suggestion to achieve the claimed inventions. (Burton 6/7/2010 Decl. ¶ 7). As noted in the specification of the application, the transitions of an inflated balloon may actually look smooth; however when the balloon is deflated, the differences are significant. (¶ [0047]; Burton 6/7/2010 Decl. ¶ 7). Indeed, the courts and the Patent Office have repeatedly warned against the use of figures for scaling undefined features. *Nystrom v. Trex Co., Inc.*, 424 F.3d 1136, 1149 (Fed. Cir. 2005) ("The district court erred in not properly applying the principles set forth in our prior precedents that arguments based on drawings not explicitly made to scale in issued patents are unavailing."); MPEP § 2125 ("PROPORTIONS OF FEATURES IN A DRAWING ARE NOT EVIDENCE OF ACTUAL PROPORTIONS WHEN DRAWINGS ARE NOT TO SCALE . . . When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value.").

Accordingly, it is respectfully submitted that neither Lee nor Bleam disclose all of the limitations of Applicants' claims, and there is no suggestion to modify the prior art to achieve Applicants' claim limitations. Specifically, Lee and Bleam do not even mention the transitions between the taper and the working length and the necks that the claimed inventions relate to. Moreover, Lee and Bleam fail to disclose the specific radii that have been claimed for the transitions. Therefore, Applicants' claims are allowable and the Examiner may withdraw the rejections of the claims. In addition to the limitations noted above, the prior art of record also fails to disclose the combination of additional limitations of Applicants' remaining dependent claims. Because each of Applicants' dependent claims incorporate all of the limitations of allowable independent claims, Applicants' dependent claims are also allowable. Therefore, any further arguments that

could be made at this time in support of the additional limitations of Applicants' dependent claims would be superfluous and is unnecessary. *In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1555 (Fed. Cir. 1983).

Conclusion

In response to the Examiner's § 112 rejections, Applicants have submitted the declaration of David G. Burton to explain how one of ordinary skill in the art would understand the claims and the specification. As previously explained by Mr. Burton in his June 7, 2010 declaration, neither Lee nor Bleam disclose any details about the transitions between the taper and the working length and the necks that the claimed inventions relate to. Therefore, the prior art of record fails to disclose or suggest all of the limitations required by the claims. Thus, Applicants' claims are allowable. Accordingly, Applicants request reconsideration and allowance of the application.

Respectfully submitted,

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